

Reduced may be stored at –18 °C or colder for up to 1 year after collection.

- Preparation of Plasma Frozen within 24 hours after Phlebotomy (PF24), Leukocytes Reduced prepared from a whole blood collection. The product can be held at room temperature up to 8 hours after collection, refrigerated at 1 to 6 °C until separated, and placed at –18 °C or below within 24 hours of whole blood collection. PF24, Leukocytes Reduced may be stored at –18 °C or colder for up to 1 year after collection.

Subsequent to this approval, the USPTO received a patent term restoration application for SOLX SYSTEM (U.S. Patent No. 6,150,085) from Haemonetics Corporation, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 5, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SOLX SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SOLX SYSTEM is 1,250 days. Of this time, 708 days occurred during the testing phase of the regulatory review period, while 542 days occurred during the approval phase. These periods of time were derived from the following dates:

- The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:*

November 24, 2009. The applicant claims November 25, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 24, 2009, which was 30 days after FDA receipt of the IND.

- The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 1, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for SOLX SYSTEM (NDA BN110059) was initially submitted on November 1, 2011.

- The date the application was approved:* April 25, 2013. FDA has verified the applicant's claim that NDA BN110059 was approved on April 25, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 894 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 24, 2017.

Leslie Kux,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0505]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 29, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0623. Also, include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Lansdowne St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle—21 CFR 189.5 and 700.27

OMB Control Number 0910-0623—Extension

FDA's regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) set forth bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA-regulated human food and cosmetics. The regulations designate certain materials from cattle as "prohibited cattle materials," including specified risk materials (SRMs), the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS) beef. Sections 189.5(c) and 700.27(c) set forth the requirements for recordkeeping and records access for FDA-regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived

from cattle. FDA issued these recordkeeping regulations under the adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), (a)(5), 601(c), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)). Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the FD&C Act's efficient enforcement. With regard to records concerning imported human food and cosmetics, FDA relied on its authority under sections 701(b) and 801(a) of the FD&C Act (21 U.S.C. 371(b) and 381(a)). Section 801(a) of the FD&C Act provides requirements with regard to imported human food and cosmetics and provides for refusal of admission of human food and cosmetics that appear to be adulterated into the United States. Section 701(b) of the FD&C Act authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act.

These requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know the following: (1) Whether cattle material may contain SRMs (brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia from animals 30 months and older and tonsils and distal ileum of the small intestine from all animals of all ages); (2) whether the source animal for cattle material was inspected and passed; (3) whether the source animal for cattle material was nonambulatory disabled or MS beef; and (4) whether tallow in human food or cosmetics contain less than 0.15 percent insoluble impurities.

FDA's regulations in §§ 189.5(c) and 700.27(c) require manufacturers and processors of human food and cosmetics manufactured from, processed with, or otherwise containing material from cattle establish and maintain records sufficient to demonstrate that the human food or cosmetics are not manufactured from, processed with, or otherwise contains prohibited cattle materials. These records must be retained for 2 years at the manufacturing

or processing establishment or at a reasonably accessible location. Maintenance of electronic records is acceptable, and electronic records are considered to be reasonably accessible if they are accessible from an onsite location. Records required by these sections and existing records relevant to compliance with these sections must be available to FDA for inspection and copying. Existing records may be used if they contain all of the required information and are retained for the required time period.

Because FDA does not easily have access to records maintained at foreign establishments, FDA regulations in §§ 189.5(c)(6) and 700.27(c)(6), respectively, require that when filing for entry with U.S. Customs and Border Protection (CBP), the importer of record of human food or cosmetics manufactured from, processed with, or otherwise containing cattle material must affirm that the human food or cosmetics were manufactured from, processed with, or otherwise containing-cattle material and must affirm that the human food or cosmetics were manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. In addition, if human food or cosmetics were manufactured from, processed with, or otherwise containing-cattle material, the importer of record must provide within 5 business days records sufficient to demonstrate that the human food or cosmetics were not manufactured from, processed with, or otherwise contains prohibited cattle material, if requested.

Under FDA's regulations, FDA may designate a country from which cattle materials inspected and passed for human consumption are not considered prohibited cattle materials, and their use does not render human food or cosmetics adulterated. Sections 189.5(e) and 700.27(e) provide that a country seeking to be designated must send a written request to the Director of the Center for Food Safety and Applied Nutrition (CFSAN Director). The information the country is required to submit includes information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether SRMs, the small intestine of

cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, or MS beef from the country seeking designation should be considered prohibited cattle materials. FDA uses the information to determine whether to grant a request for designation and to impose conditions if a request is granted.

Sections 189.5 and 700.27 further state that countries designated under §§ 189.5(e) and 700.27(e) will be subject to future review by FDA to determine whether their designations remain appropriate. As part of this process, FDA may ask designated countries to confirm their BSE situation and that the information submitted by them, in support of their original application, has remained unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate. Therefore, designated countries may respond to periodic FDA requests by submitting information to confirm their designations remain appropriate. FDA uses the information to ensure their designations remain appropriate.

Description of Respondents: Respondents to this information collection include manufacturers, processors, and importers of FDA regulated human food, including dietary supplements, and cosmetics manufactured from, processed with, or otherwise containing material derived from cattle, as well as, with regard to §§ 189.5(e) and 700.27(e), foreign governments seeking designation under those regulations.

In the **Federal Register** of June 15, 2017 (82 FR 27501), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments. One comment was unrelated to the information collection; one comment noted that the length of time to keep records was insufficient but offered no suggested timeframe; and one comment supported the information collection. After evaluating these comments FDA will not revise the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
189.5(c)(6) and 700.27(c)(6)	54,825	1	54,825	0.033 (2 minutes)	1,809
189.5(e) and 700.27(e); request for designation	1	1	1	80	80

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
189.5(e) and 700.27(e); response to request for review by FDA.	1	1	1	26	26
Total	1,915

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Domestic facilities	697	52	36,244	0.25 (15 minutes)	9,061
Foreign facilities	916	52	47,632	0.25 (15 minutes)	11,908
Total	20,969

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Except where otherwise noted, this estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle" published in the **Federal Register** of October 11, 2006 (71 FR 59653).

Reporting: FDA's regulations in §§ 189.5(c)(6) and 700.27(c)(6) impose a reporting burden on importers of human food and cosmetics manufactured from, processed with, or otherwise containing cattle material. Importers of these products must affirm that the human food or cosmetics are not manufactured from, processed with, or otherwise contain prohibited cattle materials and must affirm that the human food or cosmetics were manufactured in accordance with the applicable requirements of §§ 189.5 or 700.27. The affirmation is made by the importer of record at CBP entry. Affirmation by importers is expected to take approximately 2 minutes per entry line. Table 1 shows 54,825 lines of human food and cosmetics likely to contain cattle materials are imported annually. The reporting burden of affirming whether import entry lines contain cattle-derived materials is estimated to take 1,809 hours annually (54,825 lines × 2 minutes per line).

FDA's estimate of the reporting burden for designation under §§ 189.5 and 700.27 is based on its experience and the average number of requests for designation received in the past 3 years. In the last 3 years, FDA has not received any requests for designation. Thus, FDA estimates that one or fewer will be received annually in the future. Based

on this experience, FDA estimates the annual number of new requests for designation will be one. FDA estimates that preparing the information required by §§ 189.5 and 700.27 and submitting it to FDA in the form of a written request to the CFSAN Director will require a burden of approximately 80 hours per request. Thus, the burden for new requests for designation is estimated to be 80 hours annually, as shown in table 1, row 2.

Under §§ 189.5(e) and 700.27(e), designated countries are subject to future review by FDA and may respond to periodic FDA requests by submitting information to confirm their designations remain appropriate. In the last 3 years, FDA has not requested any reviews. Thus, FDA estimates that one or fewer will occur annually in the future. FDA estimates that the designated country undergoing a review in the future will need one-third of the time it took preparing its request for designation to respond to FDA's request for review, or 26 hours (80 hours × 0.33 = 26.4 hours, rounded to 26). The annual burden for reviews is estimated to be 26 hours, as shown in table 1, row 3. The total reporting burden for this information collection is estimated to be 1,915 hours annually.

Recordkeeping: FDA estimates that there are 697 domestic facility relationships and 916 foreign facility relationships consisting of the following facilities: An input supplier of cattle-derived materials that requires records (the upstream facility) and a purchaser of cattle-derived materials requiring documentation (this may be a human food or cosmetics manufacturer or processor). The recordkeeping burden of FDA's regulations in §§ 189.5(c) and

700.27(c) is the burden of sending, verifying, and storing documents regarding shipments of cattle material that is to be used in human food and cosmetics.

In this estimate of the recordkeeping burden, FDA treats these recordkeeping activities as shared activities between the upstream and downstream facilities. It is in the best interests of both facilities in the relationship to share the burden necessary to comply with the regulations; therefore, FDA estimates the time burden of developing these records as a joint task between the two facilities. Thus, FDA estimates that this recordkeeping burden will be about 15 minutes per week, or 13 hours per year, and FDA assumes that the recordkeeping burden will be shared between two entities (*i.e.*, the ingredient supplier and the manufacturer of finished products). Therefore, the total recordkeeping burden for domestic facilities is estimated to be 9,061 hours (13 hours × 697), and the total recordkeeping burden for foreign facilities is estimated to be 11,908 hours (13 hours × 916), as shown in table 2.

Dated: November 24, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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